NADA, device premarket approval application, or biologics license, in whole or in part, or revoking a device product development protocol or notice of completion, or declaring that such a protocol has not been completed, and stating the effective date of the order; and

(2) If the order involves withdrawal of approval of an NADA, forthwith revoke, in whole or in part, the applicable regulation, under section 512(i) of the act.

(b) If a person who is subject to a notice of opportunity for hearing under §12.21(b) requests a hearing and others do not, the Commissioner may issue a final order covering all the drug or device products at once or may issue more than one final order covering different drug or device products at different times.

Subpart C—Appearance and Participation

§12.40 Appearance.

(a) A person who has filed a notice of participation under §12.45 may appear in person or by counsel or other representative in any hearing and, subject to §12.89, may be heard concerning all relevant issues.

(b) The presiding officer may strike a person's appearance for violation of the rules of conduct in §12.90.

§12.45 Notice of participation.

(a) Within 30 days after publication of the notice of hearing under §12.35, a person desiring to participate in a hearing is to file with the Dockets Management Branch under §10.20 a notice of participation in the following form:

(Date)

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

NOTICE OF PARTICIPATION

Docket No. ____

Under 21 CFR part 12, please enter the participation of:

(Name) _____
(Street address) _____
(City and State) _____
(Telephone number) _____

Service on the above will be accepted by:

(Name) _____
(Street address) _____
(City and State) _____
(Telephone number) _____

The following statements are made as part of this notice of participation:

A. *Specific interests.* (A statement of the specific interest of the person in the proceeding, including the specific issues of fact concerning which the person desires to be heard. This part need not be completed by a party to the proceeding.)

B. *Commitment to participate.* (A statement that the person will present documentary evidence or testimony at the hearing and will comply with the requirements of 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, with the requirements of 21 CFR 13.25.)

(Signed) _____

(b) An amendment to a notice of participation should be filed with the Dockets Management Branch and served on all participants.

(c) No person may participate in a hearing who has not filed a written notice of participation or whose participation has been stricken under paragraph (e) of this section.

(d) The presiding officer may permit the late filing of a notice of participation upon a showing of good cause.

(e) The presiding officer may strike the participation of a person for nonparticipation in the hearing or failure to comply with any requirement of this subpart, e.g., disclosure of information as required by §12.85 or the prehearing order issued under §12.92. Any person whose participation is stricken may petition the Commissioner for interlocutory review.

[44 FR 22339, Apr. 13, 1979, as amended at 46 FR 8456, Jan. 27, 1981; 59 FR 14364, Mar. 28, 1994]

§12.50 Advice on public participation in hearings.

(a) *Designated agency contact.* All inquiries from the public about scheduling, location, and general procedures should be addressed to the Deputy Commissioner for Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or telephone 301–443–3480. The staff of the Associate Commissioner for Regulatory Affairs will attempt to respond promptly to all inquiries from members of the public,

as well as to simple requests for information from participants in hearings.

(b) *Hearing schedule changes.* Requests by hearing participants for changes in the schedule of a hearing or for filing documents, briefs, or other pleadings should be made in writing directly to the Administrative Law Judge (HF–3), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) *Legal advice to individuals.* FDA does not have the resources to provide legal advice to members of the public concerning participation in hearings. Furthermore, to do so would compromise the independence of the Commissioner's office and invite charges of improper interference in the hearing process. Accordingly, the Deputy Commissioner for Policy (HF–22) will not answer questions about the strengths or weaknesses of a party's position at a hearing, litigation strategy, or similar matters.

(d) *Role of the office of the Chief Counsel.* Under no circumstances will the office of the Chief Counsel of FDA directly provide advice about a hearing to any person who is participating or may participate in the hearing. In every hearing, certain attorneys in the office are designated to represent the center or centers whose action is the subject of the hearing. Other members of the office, including ordinarily the Chief Counsel, are designated to advise the Commissioner on a final decision in the matter. It is not compatible with these functions, nor would it be professionally responsible, for the attorneys in the office of the Chief Counsel also to advise other participants in a hearing, or for any attorney who may be called on to advise the Commissioner to respond to inquiries from other participants in the hearing, for such participants may be urging views contrary to those of the center involved or to what may ultimately be the final conclusions of the Commissioner. Accordingly, members of the office of the Chief Counsel, other than the attorneys responsible for representing the center whose action is the subject of the hearing, will not answer questions about the hearing from any participant or potential participant.

(e) *Communication between participants and attorneys.* Participants in a hearing may communicate with the attorneys responsible for representing the center whose action is the subject of the hearing, in the same way that they may communicate with counsel for any other party in interest about the presentation of matters at the hearing. It would be inappropriate to bar discussion of such matters as stipulations of fact, joint presentation of witnesses, or possible settlement of hearing issues. Members of the public, including participants at hearings, are advised, however, that all such communications, including those by telephone, will be recorded in memoranda that can be filed with the Dockets Management Branch.

[44 FR 22329, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985; 54 FR 9035, Mar. 3, 1989; 58 FR 17096, Apr. 1, 1993]

Subpart D—Presiding Officer

§ 12.60 Presiding officer.

The presiding officer in a hearing will be the Commissioner, a member of the Commissioner's office to whom the responsibility for the matter involved has been delegated, or an administrative law judge qualified under 5 U.S.C. 3105.

§ 12.62 Commencement of functions.

The functions of the presiding officer begin upon designation and end upon the filing of the initial decision.

§ 12.70 Authority of presiding officer.

The presiding officer has all powers necessary to conduct a fair, expeditious, and orderly hearing, including the power to—

(a) Specify and change the date, time, and place of oral hearings and conferences;

(b) Establish the procedures for use in developing evidentiary facts, including the procedures in § 12.92(b) and to rule on the need for oral testimony and cross-examination under § 12.87(b);

(c) Prepare statements of the areas of factual disagreement among the participants;

(d) Hold conferences to settle, simplify, or determine the issues in a hearing or to consider other matters that may expedite the hearing;